

**From:** "Zimmerman, Chris" <CZimmerman@amerisourcebergen.com>  
**Sent:** Thu, 13 Aug 2015 19:44:50 -0400 (EDT)  
**To:** "Mays, Steve" <SMays@amerisourcebergen.com>; "Gundy, Bruce" <BGundy@amerisourcebergen.com>  
**Subject:** Fwd: FDA Okays OxyContin for Some Pediatric Patients

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Sent from my iPhone

Begin forwarded message:

**From:** "Cherveny, Eric" <ECherveny@amerisourcebergen.com>  
**Date:** August 13, 2015 at 6:50:07 PM EDT  
**To:** "May, David" <DMay@amerisourcebergen.com>, "Hartman, Sharon" <SHartman@amerisourcebergen.com>, "Zimmerman, Chris" <CZimmerman@amerisourcebergen.com>, "Ross, Paul" <PRoss@amerisourcebergen.com>  
**Subject:** RE: FDA Okays OxyContin for Some Pediatric Patients

I agree! It sounds like something you'd see on a South Park episode!

Eric Cherveny  
Director – Diversion Control  
AmerisourceBergen Corporation  
610/727-7362  
102-7362 (Global Extension)

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**From:** May, David  
**Sent:** Thursday, August 13, 2015 6:44 PM  
**To:** Hartman, Sharon; Cherveny, Eric; Zimmerman, Chris; Ross, Paul  
**Subject:** RE: FDA Okays OxyContin for Some Pediatric Patients

I have an idea, let's ask the drug manufacturer who was sued for hundreds of millions of dollars by the federal government for essentially creating and making the opioid abuse problem what it is today, destroying countless lives in the process, to do a study of the impact of those same drugs they themselves have manufactured on children. Then, we'll accept their "findings", which surprisingly enough indicate that they can safely be administered to children under conditions that they've recommended. Has someone made this up – is this a joke?

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**From:** Hartman, Sharon  
**Sent:** Thursday, August 13, 2015 6:13 PM  
**To:** May, David; Cherveny, Eric; Zimmerman, Chris; Ross, Paul  
**Cc:** Hartman, Sharon  
**Subject:** FW: FDA Okays OxyContin for Some Pediatric Patients

**Oh boy... I would be the last person to ever want to see a child in pain when there is a safe solution but this frightens me.**

**FDA Okays OxyContin for Some Pediatric Patients**  
Megan Brooks

August 13, 2015

The US Food and Drug Administration (FDA) has approved the opioid oxycodone (*OxyContin*, Purdue Pharma LP) for pediatric patients aged 11 to 16 years with pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

"We requested the manufacturer of the pain management drug OxyContin perform studies evaluating safety and other important information about oxycodone and OxyContin when used in pediatric patients. These studies supported a new pediatric indication for OxyContin in patients 11 to 16 years old, and provided prescribers with helpful information about the use of OxyContin in pediatric patients," Sharon Hertz, MD, director, Division of Anesthesia, Analgesia, and Addiction Products, Office of New Drugs, at the Center for Drug Evaluation and Research (CDER), said in a "CDER conversation" posted on the FDA website.

"The new study data and resulting pediatric indication for OxyContin give doctors more specific information on how to safely manage pain in their pediatric patients following these types of surgery or traumas," she said.

Unlike adults, pediatric patients must already be responding to and tolerating a minimum opioid dose equal to at least 20 mg of oxycodone per day for 5 consecutive days before they can be prescribed an equivalent dose of OxyContin, Dr. Hertz said.

"This way, the doctor knows that their patient tolerates and responds appropriately to opioids and knows the amount of opioid treatment needed to manage the patient's pain. When appropriate, the doctor can then convert their patient over to an OxyContin dose that is tailored to their individual needs," she noted.

"OxyContin is not intended to be the first opioid drug used in pediatric patients, but the data show that changing from another opioid drug to OxyContin is safe if done properly," Dr Hertz said.

The warnings and precautions for pediatric patients taking this drug are the same as for adults. The full label can be found [here](#).

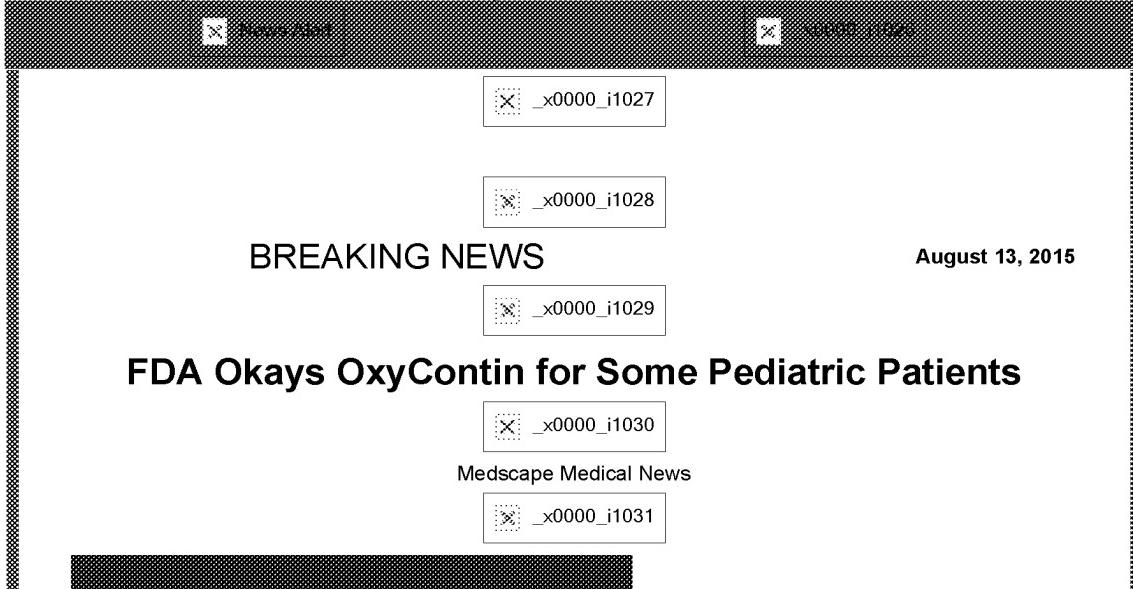
The FDA will require Purdue Pharma to conduct postmarketing studies aimed at assessing the safe use of the product in children.

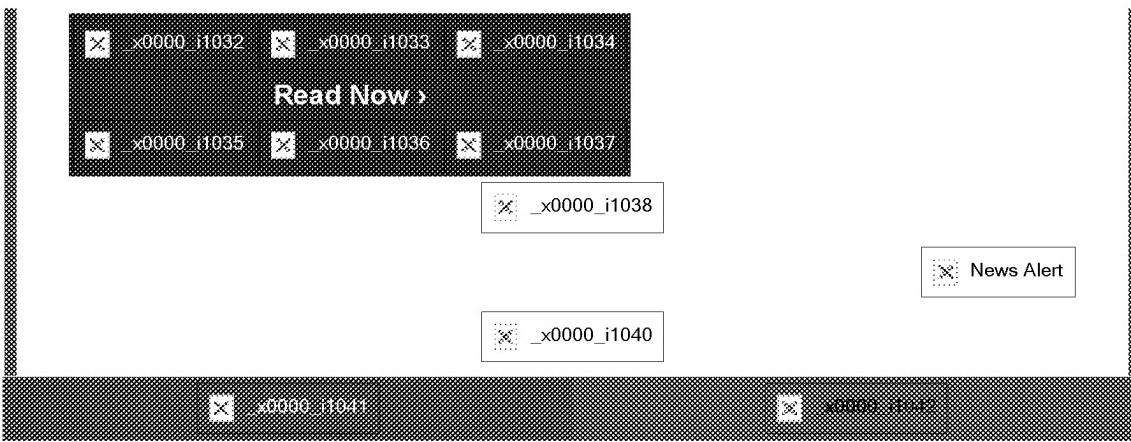
Sharon Hartman, RPh  
AmerisourceBergen  
Director, Pharmacy Compliance and Diversion Control  
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**From:** Medscape News Alert [mailto:[Medscape News Alert@mail.medscape.com](mailto:Medscape_News_Alert@mail.medscape.com)]  
**Sent:** Thursday, August 13, 2015 4:47 PM  
**To:** Hartman, Sharon  
**Subject:** FDA Okays OxyContin for Some Pediatric Patients

Breaking medical news alert for August 13, 2015.





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